REMARKS

These remarks are made in response to the office action mailed February 21, 2007.

Claim 35

Claim 35, as now presented, relates to a spectral acquisition method that includes positioning a pharmaceutical tablet within an optical field of view of an acquisition system. Material is then repeatedly removed from the tablet while it remains in position within the field of view. After each removal step, a spectral image of the tablet is acquired by the acquisition system. The spectral images are assembled into a three-dimensional data representation that includes spectral information for positions in three spatial dimensions.

Repeatedly removing material and acquiring spectral images of a tablet while it remains in position within a field of view of an acquisition system allows the system to acquire a series of well-registered spectral images of interior portions of the tablet. These can be assembled into a three-dimensional spectral data cube that maps the positions of domains of the different chemical species in the tablet. The tablet's manufacturer can then use the data cube to evaluate how well the ingredients are distributed inside the tablet.

Understanding the distribution of ingredients in finished pharmaceutical tablets is very important, because individuals often break them into smaller pieces. Breaking a poorly mixed tablet in half, for example, might create two halves of highly different dosage. This could create a risk that a user would receive too much or too little of the tablet's active ingredient. This problem is potentially even more dangerous where tablets are broken into thirds, quarters, or even smaller pieces, because of the possibility that the user might receive a dose of medication that is off by a factor of three or more. The invention can help to solve this problem by providing pharmaceutical manufacturers with a method that permits them to accurately understand, in three dimensions, how well the ingredients are distributed in their tablets. To the knowledge of the inventors, no other

practical method can provide manufacturers with such complete and accurate pictures of the insides of their finished tablets.

Claim 35 stands rejected as anticipated by Horigane. Horigane discloses an apparatus for preparing a material for analysis. This apparatus holds material in a holding unit and uses a cutter to form a cut face or cut rift. The so-prepared material is then taken, together with the holding unit, and set on an analysis apparatus (col. 7, lines 52-55).

But nowhere does Horigane disclose or suggest that his apparatus should repeatedly remove material and acquire spectral images of a tablet while it remains in position within a field of view of an acquisition system. Horigane does not disclose cutting any single item more than once, does not disclose cutting or taking images within the field of view of an acquisition system, and does not even disclose taking more than one measurement for any single item. Instead, Horigane discloses cutting an item once and then moving it to an analysis station. Horigane therefore fails to disclose the elements of claim 35, as now amended, and the anticipation rejection should be withdrawn.

Horigane's system is also unsuitable for obtaining the highest quality three-dimensional images because items are moved between cutting and analysis steps. While this movement may not be important in the case of a single measurement, it could cause potentially serious registration errors if it were used for repeated images to be assembled into a multidimensional data set. If two adjacent images are slightly misregistered, for example, individual particles that span between them may appear to be broken up and look like smaller particles. Horigane's teachings therefore fail to disclose or suggest the invention as now claimed in amended claim 35.

The remaining prior art of record also fails to disclose the invention as now presented in amended claim 35. For example, Nelson discloses a volumetric imaging method for semiconductor wafers, but this technique is only suitable for use with transparent materials. Moreover, Nelson only discloses a 489 micron depth of field, which is around an order of magnitude thinner than common pharmaceutical tablets, and he provides no indication that his technique could be extended to much thicker dimensions. Nelson's method is simply unsuitable for pharmaceuticals.

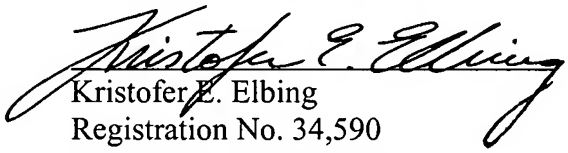
There is also no suggestion in the Nelson patent that his system should be modified to be applied to thicker non-transparent items such as pharmaceutical tablets. Nelson even points away from such changes by touting his method as rapid and non-invasive (paragraph [0213]). It is difficult to see how one of ordinary skill of the art would modify Nelson's system in ways that are suitable for use with pharmaceuticals without sacrificing these benefits. Neither Nelson nor any of the other prior art documents of record discloses or suggests the invention as it is now claimed in amended claim 35.

Independent claims 2, 16, 23, and 28 also distinguish over the prior art of record for at least reasons similar to those advanced in claim 35. The remaining claims are dependent and should be allowable for at least the reason that they depend on an allowable claim.

This application should now be in condition for allowance, and such action is respectfully requested. Should further questions arise concerning this application, patent office personnel are invited to call Applicants' representative at the number listed below. The Commissioner is hereby authorized to charge any additional fees that may be required, or credit any overpayment, to Deposit Account No. 50-0750.

Respectfully submitted,

September 21, 2007
Dated



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